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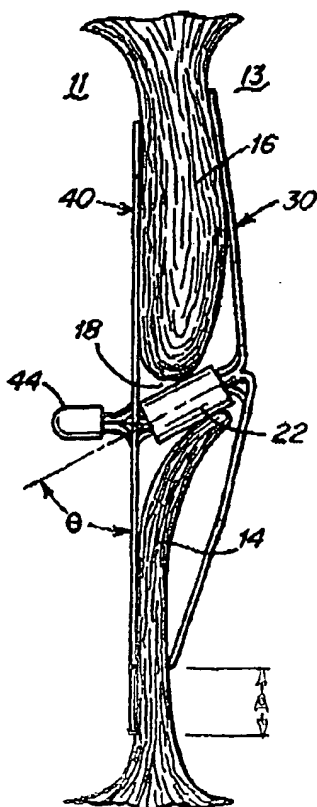
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(71) Applicant (for all designated States except US): NMT MEDICAL, INC. [US/US]; 27 Wormwood Street, Boston, MA 02210 (US).
(72) Inventor; and
(75) Inventor/Applicant (for US only): CHANDUSZKO, Andrzej, J. [US/US]; 65 Greentree Lane, Apt. 48, Weymouth, MA 02190 (US).
(74) Agents: CAVANAUGH, David, L. et al.; Hale and Dorr LLP, 60 State Street, Boston, MA 01209 (US).
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(54) Title: PATENT FORAMEN OVALE (PFO) CLOSURE DEVICE WITH RADIAL AND CIRCUMFERENTIAL SUPPORT



(57) Abstract: The present invention provides a device for occluding an anatomical aperture, such as a septal defect or patent foramen ovale (PFO). The occluder includes two sides connected by an intermediate joint. Each of the sides includes at least one elongate element, which is arranged to form non-overlapping loops. Each loop has at least one radially-extending segment that is adjacent to a radially-extending segment of another loop. In at least some embodiments, at least one pair of adjacent radially-extending segments is connected. The loops of the device may be of various shapes, sizes, and configurations, and, in at least some embodiments, the loops have rounded peripheries. In some embodiments, at least one of the sides includes a tissue scaffold. When the occluder is deployed in vivo, the two sides are disposed on opposite sides of the septal tissue surrounding the aperture, thereby exerting a compressive force on the septal tissue that is distributed along both the outer periphery of the occluder and the radiallyextending segments.

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**PATENT FORAMEN OVALE (PFO) CLOSURE DEVICE
WITH RADIAL AND CIRCUMFERENTIAL SUPPORT**

Field of the Invention

[0001] The present invention relates generally to an occlusion device for the closure of physical anomalies like septal apertures, such as patent foramen ovale and other septal and vascular defects.

Background of the Invention

[0002] A patent foramen ovale (PFO), illustrated in Figure 1, is a persistent, one-way, usually flap-like opening in the wall between the right atrium 11 and left atrium 13 of the heart 10. Because left atrial (LA) pressure is normally higher than right atrial (RA) pressure, the flap usually stays closed. Under certain conditions, however, right atrial pressure can exceed left atrial pressure, creating the possibility that blood could pass from the right atrium 11 to the left atrium 13 and blood clots could enter the systemic circulation. It is desirable that this circumstance be eliminated.

[0003] The foramen ovale serves a desired purpose when a fetus is gestating in utero. Because blood is oxygenated through the umbilical chord, and not through the developing lungs, the circulatory system of a heart in a fetus allows the blood to flow through the foramen ovale as a physiologic conduit for right-to-left shunting. After birth, with the establishment of pulmonary circulation, the increased left atrial blood flow and pressure results in functional closure of the foramen ovale. This functional closure is subsequently followed by anatomical closure of the two over-lapping layers of tissue: septum primum 14 and septum secundum 16. However, a PFO has been shown to persist in a number of adults.

[0004] The presence of a PFO is generally considered to have no therapeutic consequence in otherwise healthy adults. Paradoxical embolism via a PFO is considered in the diagnosis for patients who have suffered a stroke or transient ischemic attack (TIA) in the presence of a PFO and without another cause of ischemic stroke. While there is currently no definitive proof for a cause-effect relationship, many studies have confirmed a strong association between the presence of a PFO and the risk for paradoxical embolism or stroke. In addition, there is significant evidence that patients with PFO who have had a cerebral vascular event are at increased risk for future, recurrent cerebrovascular events.

[0005] Accordingly, patients with an increased future risk are considered for prophylactic medical therapy to reduce the risk of a recurrent embolic event. These patients are commonly treated with oral anticoagulants, which have the potential for adverse side effects, such as hemorrhaging, hematoma, and interactions with a variety of other drugs. The use of these drugs can alter a person's recovery and necessitate adjustments in a person's daily living pattern.

[0006] In certain cases, such as when anticoagulation is contraindicated, surgery may be necessary or desirable to close the PFO. The surgery would typically include suturing a PFO closed by attaching septum secundum to septum primum. This sutured attachment can be accomplished with either an interrupted or a continuous stitch and is a common way a surgeon shuts a PFO under direct visualization.

[0007] Umbrella devices and a variety of other similar mechanical closure designs, developed initially for percutaneous closure of atrial septal defects (ASDs), have been used in some instances to close PFOs. These devices have the potential to allow patients to avoid the potential side effects often associated with anticoagulation therapies

and the risks of invasive surgery. However, umbrella devices and the like that are designed for ASDs are not optimally suited for use as a PFO closure device.

[0008] Currently available designs of septal closure devices present drawbacks, including technically complex implantation procedures. Additionally, there are not insignificant complications due to thrombus, fractures of the components, conduction system disturbances, perforations of heart tissue, and residual leaks. Many devices have high septal profile and may include large masses of foreign material, which may lead to unfavorable body adaptation of a device. Since ASD devices are designed to occlude a hole, many lack anatomic conformability to the PFO flap-like anatomy. That is, when inserting an ASD device to close a PFO, the narrow opening and the thin flap may form impediments to proper deployment. Even if an occlusive seal is formed, the device may be deployed in the heart on an angle, which could leave some components not securely seated against the septum, thereby risking thrombus formation due to hemodynamic disturbances. Finally, some septal closure devices are complex to manufacture, which may result in lack of consistency in product performance.

[0009] The present invention is designed to address these and other deficiencies of the prior art septal closure devices.

Summary of the Invention

[0010] The present invention provides a device for occluding an anatomical aperture, such as a septal defect or a PFO. This occluder includes two sides connected by an intermediate joint. Each of the sides includes at least one wire or other elongate element for structural support (referred to collectively as "wire"), which is arranged to form non-overlapping loops. Each loop has at least one radially-extending segment that

is adjacent to a radially-extending segment of another loop. In at least some embodiments, at least one pair of adjacent radially-extending segments is connected. The loops of the device may be of various shapes and sizes. In at least some embodiments, the loops have rounded peripheries. The configuration of the loops and sides of the occluder are varied according to different embodiments of the invention. In some embodiments, at least one of the sides includes a tissue scaffold.

[0011] The wires forming the occluders of the present invention may be constructed of various biocompatible materials. In some embodiments, the wires are formed of shape memory materials, *e.g.* nitinol. In other embodiments, the wires are formed of polymers, bioabsorbable polymers, or combinations thereof.

[0012] The occluder according to the present invention is designed such that, when deployed *in vivo*, the two sides are disposed on opposite sides of the septal tissue surrounding the aperture, *i.e.* septum primum and septum secundum. Thus, the two sides exert a compressive force on the septal tissue that is distributed along both the outer periphery of the occluder and the radially-extending segments. In at least some embodiments, the radially-extending segments increase the stiffness of the occluder, thereby preventing the occluder from becoming dislodged from its intended delivery site. In at least some embodiments, the flexible, rounded peripheries of the loops prevent the occluder from inflicting trauma upon the septal tissue as the heart contracts. In at least some embodiments of the present invention, the occluder is repositionable and/or retrievable. These and other advantageous features of the present invention will be explained in more detail in connection with the following illustrations.

Brief Description of the Drawings

[0013] Figures 1 is a schematic representation of a human heart including a septal defect;

[0014] Figure 2 is a top view of an occluder according to one embodiment of the invention;

[0015] Figure 3 is a front elevational view of the distal side of the occluder of Figure 2;

[0016] Figure 4 is a front elevational view of the proximal side of the occluder of Figure 2;

[0017] Figure 5 is a front elevational view of the occluder of Figure 2;

[0018] Figures 6A and 6B are a side view and a front elevational view, respectively, of an occluder according to another embodiment of the present invention;

[0019] Figure 7 is a side elevational view of the occluder of Figures 6A and 6B deployed *in vivo*;

[0020] Figure 8 is a front elevational view of the distal side of an occluder according to a further embodiment of the present invention;

[0021] Figure 9 is a front elevational view of the proximal side of an occluder according to still another embodiment of the present invention;

[0022] Figures 10A-10D are front elevational views of various embodiments of the proximal side of an occluder according to the present invention;

[0023] Figure 11 is a front elevational view of the distal side of an occluder according to yet another embodiment of the present invention;

[0024] Figure 12 is a front elevational view of a proximal side of an occluder according to the present invention that includes a tissue scaffold;

[0025] Figures 13A, 13B, and 13C are perspective, side elevational, and side elevation *in vivo* views, respectively, of an occluder according to yet a further embodiment of the present invention;

[0026] Figures 14A-14E are side elevational views of one method for delivering an occluder according to the present invention to a septal defect;

[0027] Figures 15A-15E are side elevational views of a second method for delivering an occluder according to the present invention to a septal defect;

[0028] Figure 16 is a side elevational view of a partially-deployed occluder according to the present invention;

[0029] Figures 17A-17D are side elevational views of one method for retrieving an occluder according to the present invention from a septal defect; and

[0030] Figure 18 is a side elevational view of a second method for retrieving an occluder according to the present invention from a septal defect.

Detailed Description of the Invention

[0031] The present invention provides a device for occluding an aperture within body tissue. In particular and as described in detail below, the occluder of the present invention may be used for closing a PFO in the atrial septum of a heart. Although the embodiments of the invention are described with reference to a PFO, one skilled in the art will recognize that the device and method of the present invention may be used to treat

other anatomical conditions. As such, the invention should not be considered limited to any particular anatomical condition.

[0032] Figure 1 illustrates a human heart **10**, having a right atrium **11** and a left atrium **13**. The atrial septum **12** includes septum primum **14**, septum secundum **16**, and a passage **18** between the right **11** and left **13** atria. The anatomy of the septum varies widely within the population. In some people, septum primum **14** extends to and overlaps with septum secundum **16**. The septum primum **14** may be quite thin. When a PFO is present, there is a chance that blood could travel through the passage **18** between septum primum **14** and septum secundum **16** (referred to as “the PFO tunnel”).

[0033] An occluder according to one embodiment of the present invention is shown in Figures 2 through 7. As shown in Figure 2, the occluder **20** includes a distal side **30** (Figure 3) and a proximal side **40** (Figure 4). In this application, “distal” refers to the direction away from a catheter insertion location and “proximal” refers to the direction nearer the insertion location. Distal side **30** and proximal side **40** are connected by intermediate joint **22**. As shown in Figure 7, the occluder **20** may be inserted into the septal tissue **12** to prevent the flow of blood through the passage **18**, *i.e.* the occluder may extend through the PFO tunnel **18** such that the distal side **30** is located in the left atrium **13** and the proximal side **40** is located in the right atrium **11**. Various features of the occluder **20** will be described with reference to Figures 2 through 7.

[0034] The occluder **20** is constructed of wire or other elongate element for structural support, referred to collectively as “wire” **25**. The wire is arranged to form loops in both the distal **30** and proximal **40** sides of the occluder **20**. According to some embodiments of the present invention, several wires **25** are used to construct the occluder

20. According to other embodiments, the occluder may be formed of a tube using, for example, an etching or cutting process to create elongate members. The elongate members have the general structure of a wire, *i.e.* long and thin, but are not necessarily round. As used herein, the term “wire” is intended to encompass wires and elongate members (whether or not formed by an etched tube).

[0035] The wire(s) 25 may be formed of various biocompatible materials. In at least some embodiments, the occluder 20 is formed of shape memory material (*e.g.* nitinol). The thermal shape memory and/or superelastic properties of shape memory materials, *e.g.* nitinol, permit the occluder 20 to resume and maintain its intended shape *in vivo* despite being distorted during the delivery process. In particular embodiments, the occluder 20 is formed of nitinol that is austenitic at body temperature. Alternatively, or additionally, the occluder 20 may be formed of other high-strength super-alloys, such as Hastelloy® (available from Haynes International), Elgiloy®, or MP35N. In still other embodiments, occluder 20 may be formed of a polymer (*e.g.* plastics), bioabsorbable polymer, or combination of the foregoing.

[0036] The distal side 30 of the occluder 20 (also called the “anchor portion”) is shown in Figure 3. The distal side 30 includes three loops 32a, 32b, and 32c, collectively referred to as loops 32. As illustrated, the loops 32 are evenly distributed about and held together at center joint 22. Each of loops 32 has six sides of roughly the same linear dimension. Each of loops 32 has at least one segment that is adjacent to a segment of another of loops 32. Specifically, segment 33a of loop 32a is adjacent to segment 31b of loop 32b; segment 33b of loop 32b is adjacent to segment 31c of loop 32c; and segment 33c of loop 32c is adjacent to segment 31a of loop 32a.

[0037] Although the distal side 30 of the occluder 20 shown in Figure 3 includes three loops 32, occluders according to the present invention may include any number of loops 32 necessary for a given application. Occluders having less than or equal to ten loops 32 may be formed without requiring significant adjustments. In general, the stiffness of the occluder 20 increases as the number of loops 32 increases. However, occluders having more than ten loops 32 may be complicated to manufacture and deliver through the vasculature. Whatever the number of loops chosen, the loops 32 may be of varied sizes to facilitate delivery, *e.g.* to improve collapsibility of the occluder 20 or to enhance securement at the delivery site. For example, loops 32 sized to better conform with anatomical landmarks will provide enhanced securement of the occluder 20 to the septal tissue 12 *in vivo*.

[0038] Regardless of the number of loops included in distal side 30, the outer shape of the loops 32 may vary. For example, as illustrated in Figure 3, the loops 32 may be hexagonal with 120 degree angles at their bends (*i.e.* "blunt loops"). Alternatively, or additionally, the non-adjacent wire segments may be rounded to provide for a smoother perimeter. As the number of loops 32 in the distal side 30 of occluder 20 increases, it becomes desirable to round the outer perimeters of the loops 32 so as to prevent the infliction of trauma on the surrounding septal tissue 12. The loops 32 may also be formed as concave structures, such that the outermost portions of the loops 32 of the distal side 30 oppose the outermost portions of the loops 42 of the proximal side 40, as described in more detail below, thereby creating a desirable opposing force that secures the occluder 20 at its desired location *in vivo*.

[0039] As previously mentioned, the wires 25 forming loops 32 are attached at center joint 22. The adjacent segments extend radially outward from center joint 22 at a spacing of approximately 120 degrees apart. The area of septal tissue enclosed by loops 32 provides support for the distal side 30 once the occluder 20 is deployed *in vivo*. In at least one embodiment of the present invention, a connection is provided between the adjacent segments, *e.g.* between segments 33a and 31b, between segments 33b and 31c, and between segments 33c and 31a. For example, as shown in Figure 3, the adjacent segments may be connected by welds 38. Such connections provide additional stiffness to the occluder 20 and help secure the occluder 20 at its desired location *in vivo*, as described in more detail below.

[0040] The adjacent segments may be connected in a variety of ways. As previously indicated, the adjacent segments may be welded. The length of the welds 38 may extend along less than the entire radial distance of the adjacent segments. Alternatively, the adjacent segments may be connected with a tube, *e.g.* a hypo tube, having a smaller diameter than the diameter of the coupled adjacent segments. In such a configuration, the tube holds the segments together by exerting a compressive force against the wires. Numerous additional means of connecting the segments will be apparent to those skilled in the art, *e.g.* glue, clips, sutures, polymer sleeves, etc., and are considered to be within the scope of the present invention.

[0041] As previously indicated, the connections, *e.g.* welds 38, between adjacent segments provide stiffness to the distal side 30 of the occluder 20. As illustrated in Figure 3, the welds 38 may extend a significant distance along the length of the adjacent segments or may extend along only a portion of the adjacent segments. Without

connections between the adjacent segments, a force on any of loops 32 will be borne by that loop alone, and the stiffness of the distal side 30 is diminished. The capacity to vary the stiffness of the distal side 30 using various numbers and types of connections provides significant advantages. Thus, for some applications of the present invention, it may be desirable to include connections between some adjacent segments but not others or to vary the radial distance that the connections extend and/or the placement of the connections relative to the center joint 22. As the distance that the connections, *e.g.* welds 38, extend increases, the distal side 30 becomes stiffer. When the connections extend along less than half of the radial distance, the stiffness of the distal side 30 is diminished. The location of welds 38 also affects the stiffness of the occluder 50. For example, a shorter weld 38 placed at a more radially outward location along the adjacent segments will increase the stiffness and dislodgement resistance of the occluder 20. In at least some embodiments of the present invention, the connections, *e.g.* welds 38, extend along the entire length of the adjacent segments.

[0042] It should be noted that the inclusion of connections, *e.g.* welds 38, to increase the stiffness of the distal side 30 necessitates the use of a greater force to maintain the occluder 20 in reduced profile (*i.e.* in delivery configuration). The delivery system for an occluder 20 including distal side 30 having connections, *e.g.* welds 38, must, therefore, possess greater radial strength to contain such a configuration.

[0043] The proximal side 40 of the occluder 20 is shown in Figure 4. The proximal side 40 includes six loops, 42a-42f, collectively referred to as loops 42. The loops 42 are evenly distributed about tip 44. Tip 44 may be a weld, solder, or tube into which the wires would fit. Each of loops 42 is formed of wire segments that extend

radially outward from tip 44, bend approximately 180 degrees, and then extend back to intermediate joint 22. Thus, one end of each of loops 42 is attached to tip 44, while the other end of each of loops 42 is attached to intermediate joint 22. As a result, the axial position of each of loops 42 in proximal side 40 is slightly offset.

[0044] The wires forming each of loops 42 do not overlap, *i.e.* they are not intertwined or weaved. In at least one embodiment, illustrated in Figure 5, the radially-extending segments of the proximal side 40 are rotated, for example, 60 degrees with respect to the radially-extending segments of the distal side 30. Thus, as shown in Figure 5, the proximal radially-extending segments 41a, 43b, 41c, 43d, 41e, and 43f, which depart from intermediate joint 22 are rotated 60 degrees (as indicated by angle ϕ) with respect to distal radially-extending segments 31a, 33a, 31b, 33b, 31c, and 33c. Further, the loops 42 of proximal side 40 may be flat, while the loops 32 of distal side 30 may be concave, as previously described. Upon deployment *in vivo*, the opposing compressive forces exerted by the sides 30 and 40 on the septal tissue 12 are particularly advantageous.

[0045] Although the proximal side 40 of the occluder 20 shown in Figure 4 includes six loops 42, one skilled in the art will recognize that the proximal side 40 of an occluder according to the present invention may include any number of loops 42 required for a given application. However, in view of the fact that the loops 42 are non-overlapping, it may not be practical to include more than ten loops 42 in proximal side 40.

[0046] In a manner similar to that described above with regard to the distal side 30, loops 42 of proximal side 40 also include adjacent segments that may be connected.

Specifically, segment 43a of loop 42a is adjacent to segment 41b of loop 42b; segment 43b of loop 42b is adjacent to segment 41c of loop 42c; segment 43c of loop 42c is adjacent to segment 41d of loop 42d; segment 43d of loop 42d is adjacent to segment 41e of loop 42e; segment 43e of loop 42e is adjacent to segment 41f of loop 42f; and segment 43f of loop 42f is adjacent to segment 41a of loop 42a. Connections may be included between any or all of the adjacent segments. The adjacent segments may be connected using any of the connection means previously described, *e.g.* welds 48. For example, as shown in Figure 4, welds 48 are located between each pair of adjacent segments. Alternatively, as shown in Figure 9, welds 98 are located between adjacent segments that are spaced 120 degrees apart, *i.e.* between segments 43b and 41c, between segments 43d and 41e, and between segments 43f and 41a. In preferred embodiments, welds are typically located on those adjacent segments extending from intermediate joint 22, such that the segments contacting the septal tissue 12 in the right atrium 11 are stiffest. Furthermore, including connections between at least those adjacent segments that contact the septal tissue minimizes fretting and the possibility of corrosion due to metal rubbing against metal.

[0047] As indicated previously and shown in Figure 2, distal side 30 and proximal side 40 of occluder 20 are connected by intermediate joint 22. The intermediate joint 22 secures the wires of the device and, according to some embodiments, may be a weld, solder or tube. If a tube is used, the tube may have a diameter slightly less than that of the collected wires, such that the tube may be expanded during delivery and then returned to its reduced diameter following deployment of the occluder 20 *in vivo*. The reduced diameter tube will secure the wires forming loops 32 and 42 into the tube. A tube capable

of expanding and reducing may be constructed of a shape memory material, *e.g.* nitinol. Alternatively, the intermediate joint 22 may be a tube having a diameter larger than that of the collected wires; following deployment of the occluder 20 *in vivo*, this tube may be crimped to secure the wires forming loops 32 and 42.

[0048] In other embodiments of the present invention, the intermediate joint 22 may be a spring, *e.g.* a coil spring. According to these embodiments, the spring is designed to pull the proximal side 40 of occluder 20 closer to the distal side 30, thereby compressing the septal tissue 12 between the distal 30 and proximal 40 sides *in vivo*. The tension of the spring may be selected such that the occluder 20 accommodates septal tissue of varying thicknesses. When considering the characteristics of the spring, the need to accommodate septal tissue of varying thicknesses and the need to provide sufficient (but not too much) compressive force must be balanced. One skilled in the art will be capable of selecting a spring meeting these criteria for a given application.

[0049] In still further embodiments of the present invention, intermediate joint 22 is positioned at an angle θ , as shown in Figure 6. Often, anatomical anomalies have non-perpendicular apertures and are sometimes quite significantly non-perpendicular. Thus, the occluder 20 may include an angled intermediate joint 22, such that the angle of the anatomical aperture is more closely matched by the pre-formed angle θ of the occluder 20. Accordingly, the distal 30 and proximal 40 sides of occluder 20 are more likely to be seated against and minimize distortion to the septal tissue 12 surrounding the passage 18. A well-seated occluder 20 is less likely to permit blood leakage between the right 11 and left 13 atria, and the subject into which the occluder 20 has been placed is, therefore, less likely to suffer embolisms and other adverse events. Advantageously, angled

intermediate joint 22 also facilitates delivery of occluder 20, as described in more detail below, because it is angled toward the end of the delivery catheter. In at least some embodiments, the angle θ is about 0-45 degrees off the plane created by the proximal side 40. One skilled in the art will recognize that the concept of an angled intermediate joint may also be applied to septal occluders other than those disclosed herein.

[0050] When intermediate joint 22 is positioned at angle θ , distal side 30 and proximal side 40 of occluder 20 may be configured such that they are either directly opposing or, as shown in Figures 6A and 6B, offset by distance A. One skilled in the art will, of course, recognize that the configuration of either or both of distal side 30 and proximal side 40 may be adjusted such that the compressive forces applied by the distal 30 and proximal 40 sides of occluder 20 are as directly opposing as possible. However, in some clinical applications, an occluder 20 having an offset of distance A may be particularly desirable. For example, as shown in Figure 7, if the septal tissue 12 surrounding passage 18 includes a disproportionately thick portion (*e.g.* septum secundum 16 as compared to septum primum 14), the offset may be used to seat occluder 20 more securely upon septal tissue 12. Moreover, the offset A allows each of sides 30 and 40 to be centered around each side of an asymmetric defect.

[0051] When an intermediate joint 22 at angle θ is included in occluder 20, a marker is required to properly orient the occluder 20 in its intended *in vivo* delivery location. For example, platinum wire may be wrapped around one of loops 32 or 42 so as to permit visualization of the orientation of the occluder 20 using fluoroscopy. Alternatively, other types of markers may be used, *e.g.* coatings, clips, etc. As will be readily understood by one skilled in the art, the orientation of a non-symmetrical occluder

20 during delivery is of great importance. Of course, when a non-symmetrical occluder 20 is used, the periphery of the occluder 20 may be configured such that the clamping force applied by the proximal side 40 is directly opposed to that applied by the distal side 30.

[0052] Upon deployment *in vivo* (a process described in detail below), an occluder according to the present invention applies a compressive force to the overlapping layers of septal tissue 12, *i.e.* septum primum 14 and septum secundum 16. Distal side 30 is seated against the septal tissue 12 in the left atrium 13; joint 22 extends through passage 18; and proximal side 40 is seated against the septal tissue 12 in the right atrium 11. As illustrated in Figures 2, 5, and 7, the proximal 40 and distal 30 sides of occluder 20 overlap significantly, such that septum primum 14 and septum secundum 16 are “sandwiched” between them once the occluder 20 is deployed. The connected, adjacent segments provide a radially-extending compressive force, while the peripheral loops 32 and 42 provide a circumferential compressive force. Thus, the compressive forces are more evenly and more widely distributed across the surface of the septal tissue 12 surrounding the PFO. The unique combination of radially-extending, connected, adjacent segments and peripheral loops 32 and 42, therefore, provides the occluder 20 with superior dislodgement resistance as compared to prior art devices. As used herein, “dislodgement resistance” refers to the ability of an occluder 20 to resist the tendency of the force applied by the unequal pressures between the right 11 and left 13 atria (*i.e.* the “dislodging force”) to separate the occluder 20 from the septal tissue 12. Generally, a high dislodgement resistance is desirable.

[0053] Moreover, loops 32 and 42 are configured to provide occluder 20 with adequate surface area to seal the PFO. For example, the broad configuration of loops 32 and 42 increases the surface area of occluder 20. Thus, loops 32 and 42 provide sealing along a large circumference around the passage 18 (*i.e.* the PFO), thereby minimizing the possibility of leakage between the right 11 and left 13 atria.

[0054] While configured to provide sufficient circumferential sealing, loops 32 and 42 are also configured to minimize the trauma they inflict on the septal tissue 12 surrounding the PFO. Specifically, two features of loops 32 and 42 achieve this. First, the peripheries of loops 32 and 42 may be rounded. Second, the peripheries of loops 32 and 42 are formed of a single wire and are, therefore, more flexible than the interiorly-located, connected, adjacent segments, which are formed of two wires. These features minimize the overall trauma inflicted by occluder 20 on the septal tissue 12 surrounding the PFO. Accordingly, occluder 20 has a low compression resistance. As used herein, "compression resistance" refers to the ability of an occluder 20 to resist the lateral compressive force applied by the heart as it contracts during a heartbeat. Generally, an occluder that resists compressive force, *i.e.* has high compression resistance, is undesirable because its rigid configuration may cause trauma to the septal tissue 12, the right atrium 11, and/or the left atrium 13.

[0055] In heretofore known occluder designs, dislodgement resistance must usually be sacrificed in order to improve, *i.e.* minimize, compression resistance. However, the occluder 20 according to the present invention possesses both increased dislodgement resistance and minimized compression resistance. These desirable attributes are achieved by the unique combination of radially-extending, connected,

adjacent segments and peripheral loops 32 and 42 discussed above. The radially-extending, connected, adjacent segments (*i.e.* struts) increase the stiffness and, correspondingly, the dislodgment resistance of the occluder 20. The atraumatic shape of the peripheral loops 32 and 42 decreases the compression resistance of the occluder 20. In effect, because the struts are formed of double-stranded wire and the peripheries of the loops 32 and 42 are formed of single-stranded wire, the center of the occluder 20 is twice as strong as its parameter. This, correspondingly, produces the advantageous combination of increased dislodgement resistance and minimized compression resistance in occluder 20.

[0056] The dislodgement resistance of occluder 20 may be further increased without increasing the compression resistance by the inclusion of additional struts. As illustrated in Figure 8, additional struts 85a-85c, collectively referred to as additional struts 85, may be included between loops 32a-32c, *i.e.* between adjacent segments 33a and 31b, 33b and 31c, and 33c and 31a. Additional struts 85 may be of any suitable diameter, and, according to some embodiments, the diameter of additional struts 85 may vary along their length. For example, the diameter of additional struts 85 may increase as the additional struts 85 extend from intermediate joint 22 to the periphery of loops 32. Although Figure 8 depicts additional struts 85 between loops 32 of distal side 30, additional struts 85 may additionally or alternatively be included between loops 42 of proximal side 40 of occluder 20.

[0057] The configuration of the occluder 20 according to the present invention provides several further advantages. First, broad loops 32 and 42 create a large surface area for occluder 20 and thereby anchor the occluder 20 more securely *in vivo*. In

contrast, many previously known occluders include narrow loops, which afford less surface area for exertion of compressive forces and secure placement of the occluder 20. Second, the loops 32 and 42 create an occlusion perimeter that likely extends significantly beyond the passage 18. Third, loops 32 and 42 are non-overlapping, *i.e.* the wires are not intertwined or weaved. This non-overlapping configuration reduces the occurrence of fretting corrosion, which frequently occurs in prior art devices containing overlapping wires.

[0058] Occluder 20 may be modified in various ways. According to some embodiments of the present invention, loops 32 of distal side 30 and loops 42 of proximal side 40 may be formed in a variety of shapes. Four examples are illustrated in Figures 10A-10D. For convenience, only the proximal side 40 of each of these modified embodiments is depicted. However, the distal side 30 of occluder 20 may be similarly modified. The star-shaped pattern 100a shown in Figure 10A includes four large loops, referred to collectively as loops 102a. Loops 102a are centered and approximately equally spaced around tip 44. Any or all of loops 102a may include a smaller loop, collectively referred to as loops 104a, at their radial extent. Smaller loops 104a may be capable of receiving a suture to facilitate retrieval of the occluder 20.

[0059] An alternative, diamond pattern 100b is shown in Figure 10B. Diamond pattern 100b includes six diamond-shaped loops, referred to collectively as loops 102b, which are equally spaced around tip 44. Diamond pattern 100b is asymmetrically oriented, such that two of loops 102b extend further in the radial direction than the other loops 102b. This asymmetry may provide more complete and secure coverage of passage

18 than that provided by a symmetric occluder **20**. The asymmetric pattern **100b** may also facilitate the compact, percutaneous delivery of occluder **20**.

[0060] Still a further alternative, rectangular pattern **100c**, is shown in Figure 10C. Rectangular pattern **100c** includes four rectangular-shaped loops, referred to collectively as loops **102c**, which are equally spaced around tip **44**. Rectangular pattern **100c** provides extended coverage in two directions. Such a rectangular shape may be particularly suited for coverage of certain passages **18**. Loops **102c** may extend further in either the horizontal or vertical direction. As shown in Figure 10C, loops **102c** extend further in the horizontal direction.

[0061] Yet a further alternative, diamond pattern **100d**, is shown in Figure 10D. Diamond pattern **100d** includes four diamond-shaped loops, referred to collectively as loops **102d**. Two of loops **102d** are larger than the other two loops **102d**. Thus, an extended amount of coverage may be provided across the passage **18** in either the horizontal or vertical direction. As shown in Figure 10D, extended coverage is provided in the horizontal direction.

[0062] Of course, distal **30** and proximal **40** sides of occluder **20** may be configured in a combination of shapes and sizes depending on clinical needs presented by a given PFO. If required, the loops **102** in the illustrative patterns provided in Figures 10A-10D, may be rounded. The number of loops in embodiments of either the distal **30** or proximal **40** sides may be varied as necessary. As previously described, loops **102** in the illustrative patterns provided in Figures 10A-10D include adjacent segments, which may be connected by, *e.g.*, welds **108a-108d**, respectively. One skilled in the art will be able to identify the configuration(s) appropriate for a given clinical application.

[0063] According to further embodiments of the present invention, smaller loops may be included on distal side 30 and/or proximal side 40 of occluder 20 to increase the compressive force applied in close proximity to passage 18 (*i.e.* the PFO). As illustrated in Figure 11, three smaller loops 115a-115c, referred to collectively as smaller loops 115, are located on distal side 30. Smaller loops 115 are centered and equally spaced around intermediate joint 22. Although smaller loops 115a-115c in Figure 11 correspond in number and alignment with loops 32a-32c, respectively, such correspondence is not required. Moreover, smaller loops 115 need not lie entirely in the same plane as loops 32 or 42. Thus, smaller loops 115 may bend in a direction generally perpendicular to the plane in which loops 32 or 42 lie. Smaller loops 115 may be attached only to intermediate joint 22 or, alternatively, may also be connected to the adjacent segments of loops 32. In still other embodiments, smaller loops 115 may be located at the peripheries of loops 32 rather than connected to intermediate joint 22. When the smaller loops 115 are located at the peripheries of loops 32, additional wire segments may be included within loops 32 to connect the smaller loops 115 to the intermediate joint 22. One skilled in the art will be able to determine the precise configuration of smaller loops 115 appropriate for a given clinical application.

[0064] According to still further embodiments of the present invention and as illustrated in Figure 12, distal side 30 and/or proximal 40 side of occluder 20 may include a tissue scaffold 125. Tissue scaffold 125 ensures more complete coverage of passage 18 and promotes encapsulation and endothelialization of septal tissue 12, thereby further encouraging anatomical closure of septum primum 14 and septum secundum 16. Tissue scaffold 125 may be formed of any flexible, biocompatible material capable of promoting

tissue growth, including but not limited to polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM) or other bioengineered material, synthetic bioabsorbable polymeric scaffolds, other natural materials (*e.g.* collagen), or combinations of the foregoing materials. For example, tissue scaffold **125** may be formed of a thin metallic film or foil, *e.g.* a nitinol film or foil, as described in United States Patent Appln. No. 2003/0059640 (the entirety of which is incorporated herein by reference).

[0065] Adjacent segments may be stitched to tissue scaffold **125** so as to securely fasten the scaffold **125** to occluder **20**. For example, Figure 12 shows tissue scaffold **125** affixed to proximal side **40** of an occluder according to the present invention. Proximal side **40** includes six loops **42a-42f**, collectively referred to as loops **42**. Adjacent segments **43a** and **41b**, **43b** and **41c**, **43c** and **41d**, **43d** and **41e**, **43e** and **41f**, and **43f** and **41a** are attached to tissue scaffold **125** by stitches **127**. Stitches **127** increase the stiffness of occluder **20** without welding or soldering. Additionally, when the adjacent segments of loops **42** are connected to tissue scaffold **125**, the adjacent segments of loops **42** may be spaced apart a small distance (*i.e.* they need not necessarily be connected). Altering the spacing of the adjacent segments of loops **42** adjusts the stiffness of the occluder **20**, which may be desirable in certain circumstances. One skilled in the art will be able to determine those clinical applications in which the use of stitches **127** and/or spaced, adjacent segments is appropriate.

[0066] According to yet further embodiments of the present invention, the configuration of occluder **20** may be modified to produce the low-profile occluder **130** shown in Figure 13A. In this embodiment, the manufacturing process is modified to

increase the force with which the distal 30 and proximal 40 sides urge toward one another. Specifically, during manufacture, distal 30 and proximal 40 sides of occluder 20 may be crossed over each other (as shown in Figure 13B) prior to connecting the adjacent segments of loops 32 and 42 (*i.e.* while the occluder 20 is in an “unconstrained” state). This crossed-over configuration may be achieved by, for example, using the shape memory properties of a shape memory material, such as nitinol, *i.e.* forcing, *e.g.*, loops 42d and 42e of proximal side 40 through loop 32c of distal side 30 or vice versa and heat-setting the crossed-over shape. The crossed-over shape, therefore, becomes the predisposed position of occluder 20. Occluder 20 is then returned to its original, non-crossed-over state, and the adjacent segments of loops 32 and 42 are connected. The connected, adjacent segments prevent loops 42d and 42e from passing through loop 32c, and occluder 20 is, consequently, no longer capable of assuming its predisposed position. However, loops 42d and 42e of proximal side 42 still tend to bend toward distal side 30. The resulting occluder 130, shown in Figure 13A, is of low profile. Further, occluder 130 exerts a greater compressive force on the septal tissue 12 when deployed *in vivo* (as shown in Figure 13C) than at least some of the previously-described embodiments of occluder 20. This increased compressive force may be desirable in applications where the septal tissue 12 is particularly thin in one area, *i.e.* septum primum 14. The profile of occluder 130 may be lowered even further by angling tip 44 such that it is substantially parallel to proximal side 40 of occluder 130, as shown in Figure 13A. Angled tip 44 also facilitates catheter delivery of occluder 130 because angled tip 44 points toward the end of the delivery catheter.

[0067] Finally, although occluders according to the present invention have been heretofore described as including distal **30** and proximal **40** sides having different configurations, an occluder **20** according to the present invention may, alternatively, include distal **30** and proximal **40** sides having identical configurations. This identical design may provide several advantages, including ease of manufacture. Furthermore, any of the configurations described herein for either distal side **30** or proximal side **40** may be applied to either or both of distal side **30** and proximal side **40** of occluder **20**.

[0068] An occluder as described herein may be delivered to a septal defect using any of several suitable delivery techniques, two of which will be described herein. In the first delivery technique, shown in Figures 14A-14E, a delivery catheter **140** is used to deliver, *e.g.*, occluder **20**. Catheter **140** contains occluder **20** in its distorted, elongated form. As previously mentioned, in at least some embodiments, occluder **20** is formed of a shape memory material, *e.g.* nitinol, such that occluder **20** will resume its intended shape following deployment *in vivo*. As shown in Figure 14A, delivery catheter **140** is first inserted into the right atrium **11** of the subject's heart. Catheter **140** is next inserted between septum primum **14** and septum secundum **16** (*i.e.* through passage **18**, which, in this embodiment, is the PFO tunnel) and into the left atrium **13** (Figure 14B). Distal side **30** of occluder **20** is then deployed into the left atrium **13**, as shown in Figure 14C. Following deployment of distal side **30**, the catheter **140** is withdrawn through the PFO tunnel and into the right atrium **11**, such that intermediate joint **22** is deployed through the PFO tunnel (Figure 14D). Finally, proximal side **40** of occluder **20** is deployed into the right atrium **11**, and catheter **140** is withdrawn from the heart (Figure 14E). Once deployed, occluder **20** rests within the septal defect, and the distal **30** and proximal **40**

sides exert a compressive force against septum primum **14** and septum secundum **16** in the left **13** and right **11** atria, respectively, to close the PFO.

[0069] In a second delivery technique, shown in Figures 15A-15E, delivery catheter **150** includes a needle **151** capable of puncturing septum primum **14**. As illustrated in Figure 15A, septum primum **14** is long and thin and extends over septum secundum **16** in the left atrium **13**. In some clinical applications, it may be advantageous to access the left atrium **13** by puncturing septum primum **14** rather than inserting the occluder **20** through the passage **18** between septum primum **14** and septum secundum **16**. For example, some anatomical configurations include an extremely oblique passage **18** between the right atrium **11** and the left atrium **13**. Thus, according to this second delivery technique, delivery catheter **150** includes a needle **151** on its distal end and contains occluder **20** in its distorted, elongated form. Catheter **150** is first inserted into the right atrium **11** of the subject's heart (Figure 15A). Next, as shown in Figure 15B, needle **151** punctures septum primum **14**, and catheter **150** enters the left atrium **13**. Needle **151** is then retracted, and distal side **30** of occluder **20** is deployed into the left atrium **13** (Figure 15C). Following deployment of distal side **30**, catheter **150** is withdrawn through septum primum **14** and into the right atrium **11**, such that intermediate joint **22** is deployed through septum primum **14**, as shown in Figure 15D. Finally, proximal side **40** of occluder **20** is deployed into the right atrium **11**, and catheter **150** is withdrawn from the heart (Figure 15E). Once deployed, the distal **30** and proximal **40** sides of occluder **20** exert a compressive force against septum primum **14** and septum secundum **16** in the left **13** and right **11** atria, respectively, to close the PFO. When using this second delivery technique to deploy occluder **20**, intermediate joint **22** should not be

angled, *i.e.* intermediate joint **22** should be perpendicular to both the distal **30** and proximal **40** sides of the occluder **20**.

[0070] Figure 16 provides a more detailed representation of occluder **20** in its intermediate configuration between its compressed and fully-deployed states. As previously described, proximal side **40** of occluder **20** includes wire(s) **25**, which form connected, adjacent radially-extending segments and loops **42**, and tip **44**. During delivery of occluder **20**, tip **44** is attached to a delivery wire **161**, in a manner known to those skilled in the art. When the proximal side **40** of occluder **20** is being deployed in the right atrium **11**, the wire(s) **25** exit catheter **140** or **150** first, followed by tip **44**, and, finally, delivery wire **161**. Once occluder **20** has been positioned, delivery wire **161** is then fully retracted into the catheter **140** or **150** and the catheter is retracted out of the right atrium **11**.

[0071] Delivery wire **161** may be used to reposition and/or retrieve occluder **20** as shown in Figures 17A-17D. If, following partial or complete deployment, the clinician desires to reposition or retrieve occluder **20**, tip **44** may be recaptured with delivery wire **161** in catheter **170**, as shown in Figure 17A. As delivery wire **161** and tip **44** are pulled back into catheter **170**, loops **42** of proximal side **40** fold back into their delivery (*i.e.* compressed) configuration (Figure 17B) and are constrained by catheter **170**. Catheter **170** is then advanced through passage **18** and delivery wire **161** is further retracted, such that loops **32** of distal side **30** fold into their delivery configuration (Figure 17C) and are constrained by catheter **170**. Catheter **170** containing retrieved occluder **20** is then withdrawn through passage **18**, into the right atrium **11** (Figure 17D), and out of the heart.

[0072] In some embodiments according to the present invention, occluder 20 may be repositioned and/or retrieved using the alternative technique shown in Figure 18. As previously described, an occluder 20 according to the present invention may include identical distal 30 and proximal 40 sides. Thus, for example, occluder 20 may include both distal 30 and proximal 40 sides as depicted in Figure 3. In such an embodiment, proximal side 40 will not include a tip 44 for recovery by a delivery wire. An alternative method of retrieving the occluder is, therefore, required. In Figure 18, occluder 20 has been delivered (according to either of the delivery techniques described above) to the extent that proximal side 40 has been deployed in the right atrium 11 but not released from catheter 140. A thread 181, such as a suture, is attached to each of loops 42 on proximal side 40 of occluder 20. If the occluder 20 requires repositioning, then thread 181 may be retracted and loops 42 will fold back into their delivery configuration, such that occluder 20 may be repositioned or, even, completely retrieved. Once occluder 20 has been deployed correctly, thread 181 may be cut and removed via catheter 140.

[0073] One skilled in the art would recognize that the occluders described herein may be used with anti-thrombogenic compounds, including but not limited to heparin and peptides, to reduce thrombogenicity of the occluder and/or to enhance the healing response of the septal tissue 12 following deployment of the occluder *in vivo*. Similarly, the occluders described herein may be used to deliver other drugs or pharmaceutical agents (*e.g.* growth factors, peptides). The anti-thrombogenic compounds, drugs, and/or pharmaceutical agents may be included in the occluders of the present invention in several ways, including by incorporation into the tissue scaffold 125, as previously described, or as a coating, *e.g.* a polymeric coating, on the wire(s) forming the distal 30

and proximal **40** sides of the occluder. Furthermore, the occluders described herein may include cells that have been seeded within tissue scaffold **125** or coated upon the wire(s) forming the distal **30** and proximal **40** sides of the occluder.

[0074] One skilled in the art would recognize that occluders according to this invention could be used in occluding other vascular and non-vascular openings. For example, the device could be inserted into a left atrial appendage or other tunnels or tubular openings within the body.

[0075] Having described preferred embodiments of the invention, it should be apparent that various modifications may be made without departing from the spirit and scope of the invention, which is defined in the claims below.

We claim:

1. A medical device for occluding an anatomical aperture, comprising a plurality of elongate elements, wherein the elements are arranged to form non-overlapping loops such that each loop has at least one segment adjacent to a segment from another loop and wherein at least one pair of adjacent segments are connected to each other.
2. The medical device of claim 1, wherein said at least one connected pair of adjacent segments comprise radially-extending segments.
3. The medical device of claim 2, wherein said at least one connected pair of adjacent segments are welded.
4. The medical device of claim 2, wherein said plurality of elongate elements form at least two loops.
5. The medical device of claim 2, wherein said plurality of elongate elements form at least four loops and at least three pairs of adjacent segments are connected to each other.
6. The medical device of claim 2, wherein each of said non-overlapping loops forms part of the outer periphery of the device.
7. The medical device of claim 6, wherein each of said non-overlapping loops includes a rounded edge at its periphery.
8. The medical device of claim 7, wherein the outer periphery is a circle.

9. The medical device of claim 1, wherein said device includes a material selected from the group consisting of metals, shape memory materials, alloys, polymers, bioabsorbable polymers, and combinations thereof.

10. The medical device of claim 9, wherein said device includes nitinol.

11. The medical device of claim 1, wherein said elongate element includes wire.

12. The medical device of claim 1, wherein said device is machined from a single tube.

13. A device for occluding a defect in septal tissue, comprising:

a first side adapted to be disposed on one side of septal tissue with a defect and a second side adapted to be disposed on an opposite side of the septal tissue with a defect,

said first and second sides adapted to occlude the defect upon deployment at the delivery location,

said first and second sides each comprising a plurality of non-overlapping wires, wherein said wires form loops that extend from a center axis and adjacent segments of said loops are connected to each other.

14. The device of claim 13, wherein said device is adapted to center around an asymmetrically-located defect.

15. The device of claim 13, wherein said adjacent segments are welded.

16. The device of claim 13, wherein said device includes a material selected from the group consisting of metals, shape memory materials, alloys, polymers, bioabsorbable polymers, and combinations thereof.

17. The device of claim 16, wherein said device includes nitinol.

18. The device of claim 13, wherein at least one of said first and second sides further comprises a tissue scaffold.

19. The device of claim 18, wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, polyurethanes, metals, polyvinyl alcohol (PVA), extracellular matrix (ECM) or other bioengineered material, synthetic bioabsorbable polymeric scaffolds, collagen, and combinations thereof.

20. The device of claim 19, wherein said tissue scaffold includes nitinol.

21. The device of claim 19, wherein said tissue scaffold is attached to said loops of said at least one side.

22. The device of claim 13, wherein said first and second sides are connected by an intermediate joint.

23. The device of claim 22, wherein said intermediate joint is positioned so as to minimize distortion to the septal tissue surrounding the defect.

24. The device of claim 23, wherein said intermediate joint is positioned at an angle θ from said second side and wherein said angle θ is greater than 0 degrees and less than about 90 degrees.

25. A device for occluding a defect in septal tissue, comprising:

a first side adapted to be disposed on one side of the septal tissue with a defect and a second side adapted to be disposed on an opposite side of the septal tissue with a defect,

said first and second sides adapted to occlude the defect upon deployment at the delivery location,

said first and second sides each comprising a plurality of non-overlapping wires, wherein said wires form loops that extend generally radially from a center axis and include circumferential wire segments, and

wherein said radially-extending wire segments and said circumferential wire segments cooperate to provide a compressive force to the septal tissue surrounding the defect.

26. The device of claim 25, wherein said first and second sides comprise wire loops.

27. The device of claim 26, wherein each of said first and second sides comprises at least three adjacent loops.

28. The device of claim 27, wherein said radially-extending wire segments of said at least three adjacent loops are connected.

29. The device of claim 28, wherein said radially-extending wire segments of said at least three adjacent loops are welded.

30. The device of claim 28, wherein said compressive force exerted by said radially-extending wire segments of said adjacent loops is at least twice as great as that exerted by said circumferential wire segments of said adjacent loops.

31. The device of claim 25, wherein said device further comprises an intermediate joint connecting said first and second sides.

32. The device of claim 31, wherein said intermediate joint is positioned so as to minimize distortion to the septal tissue surrounding the defect.

33. The device of claim 32, wherein said intermediate joint is positioned at an angle θ from said second side and wherein said angle θ is greater than 0 degrees and less than about 90 degrees.

34. The device of claim 25, wherein said device includes a material selected from the group consisting of metals, shape memory materials, alloys, polymers, bioabsorbable polymers, and combinations thereof.

35. The device of claim 34, wherein said device includes nitinol.

36. The device of claim 25, wherein at least one of said first and second sides further comprises a tissue scaffold.

37. The device of claim 36, wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, polyurethanes, metals, polyvinyl alcohol (PVA), extracellular matrix (ECM) or other bioengineered material, synthetic bioabsorbable polymeric scaffolds, collagen, and combinations thereof.

38. The device of claim 37, wherein said tissue scaffold includes nitinol.

39. The device of claim 36, wherein said tissue scaffold is attached to said loops of said first and second sides.

40. A medical device for occluding an anatomical aperture, comprising a plurality of elongate members,

wherein said elongate members are arranged to form non-overlapping loops such that each loop has at least one segment adjacent to a segment from another loop,

wherein at least one pair said adjacent segments are connected to each other, and

a reinforcing element is associated with said adjacent segments.

41. The medical device of claim 35, wherein said elongate members are wires and at least one connected pair of adjacent segments comprise radially-extending segments.

42. The medical device of claim 41, wherein said at least one connected pair of adjacent segments are welded.

43. The medical device of claim 41, wherein said plurality of wires form at least two loops.

44. The medical device of claim 41, wherein said plurality of wires form at least four loops and at least three pairs of adjacent wire segments are connected to each other.

45. The medical device of claim 40, wherein a part of each of said non-overlapping loops forms part of the outer periphery of the device.

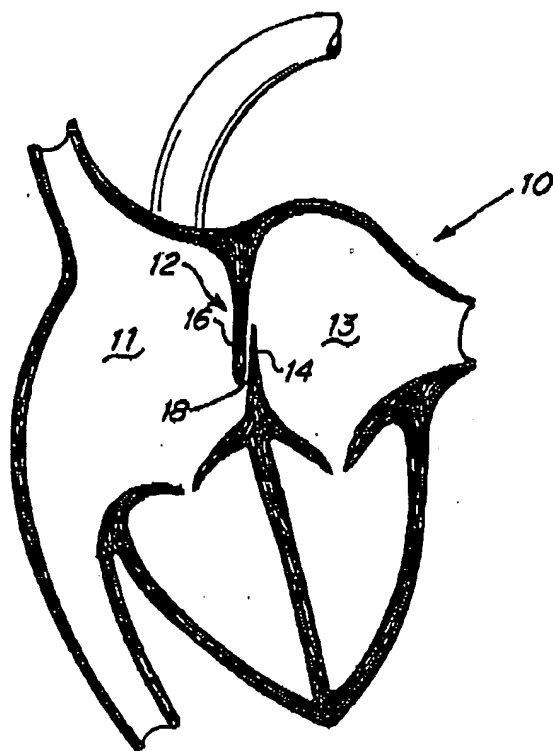
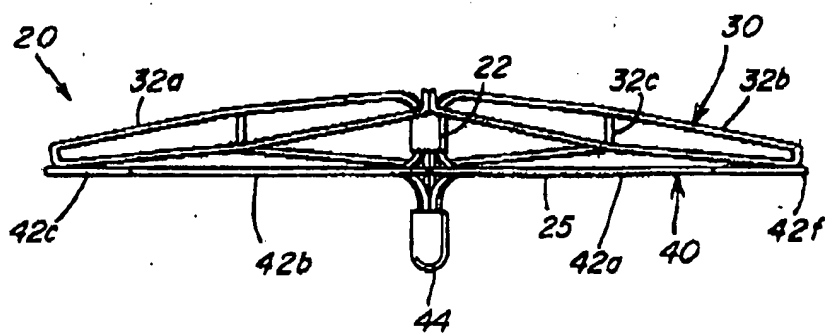
46. The medical device of claim 45, wherein each of said non-overlapping loops includes a rounded edge at its periphery to minimize trauma to tissue.

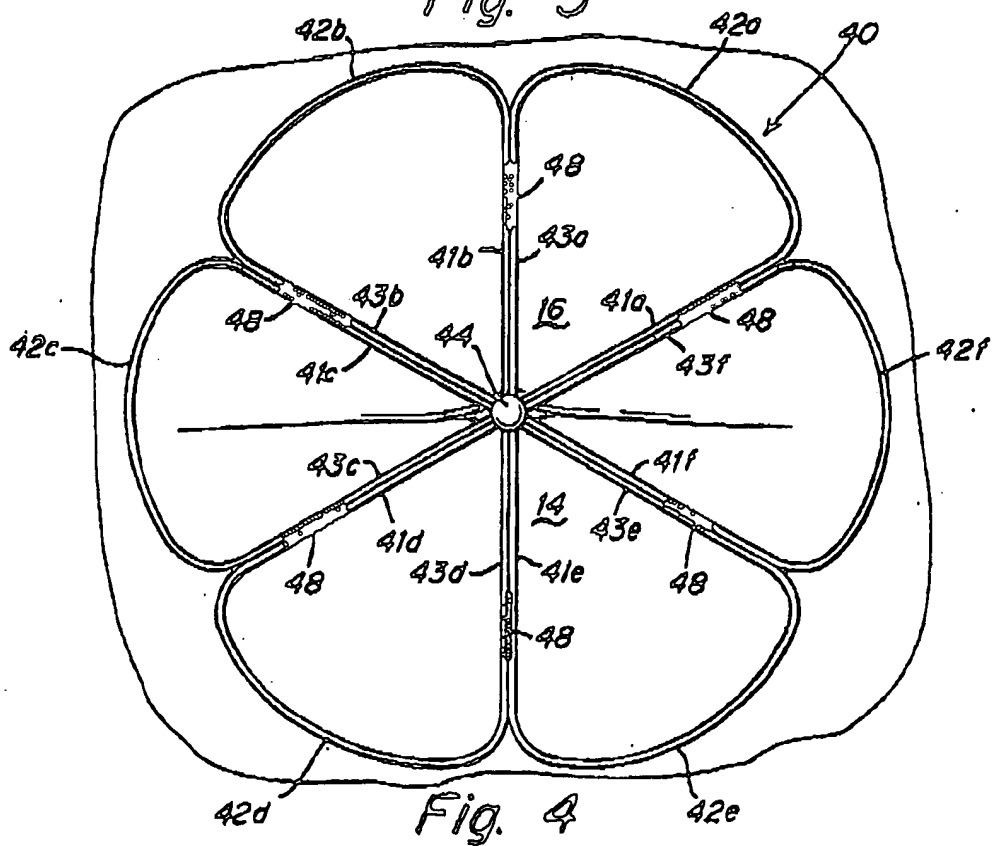
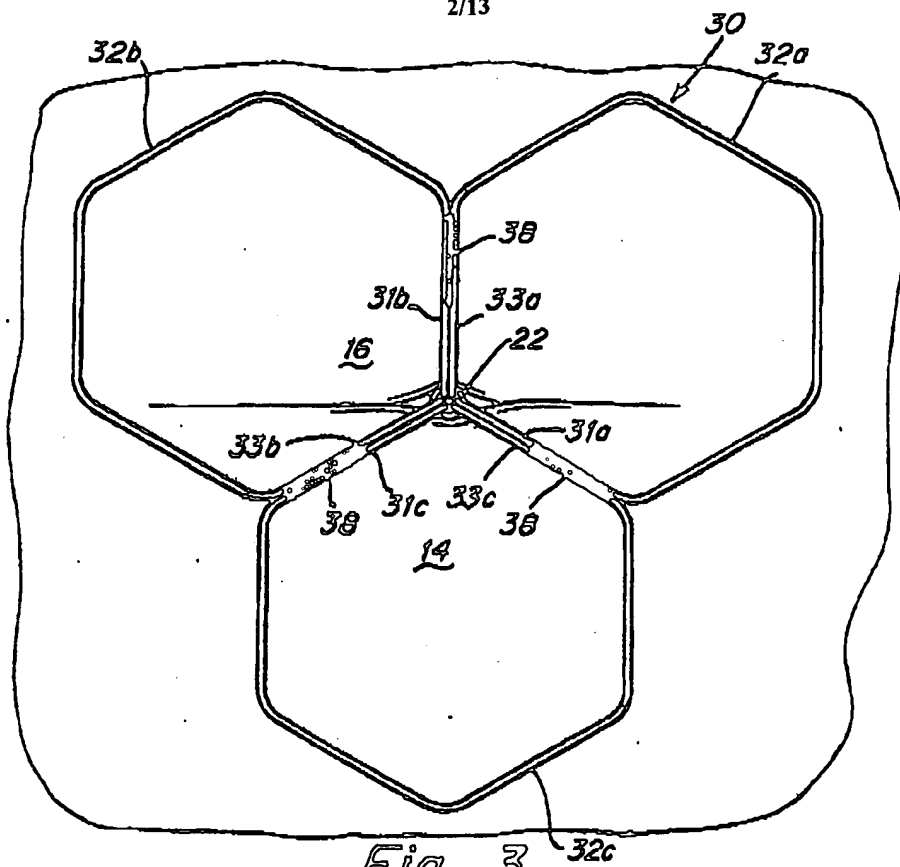
47. The medical device of claim 46, wherein the outer periphery is a circle.

48. The device of claim 40, wherein said device includes a material selected from the group consisting of metals, shape memory materials, alloys, polymers, bioabsorbable polymers, and combinations thereof.

49. The device of claim 48, wherein said device includes nitinol.

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*Fig. 1**Fig. 2*



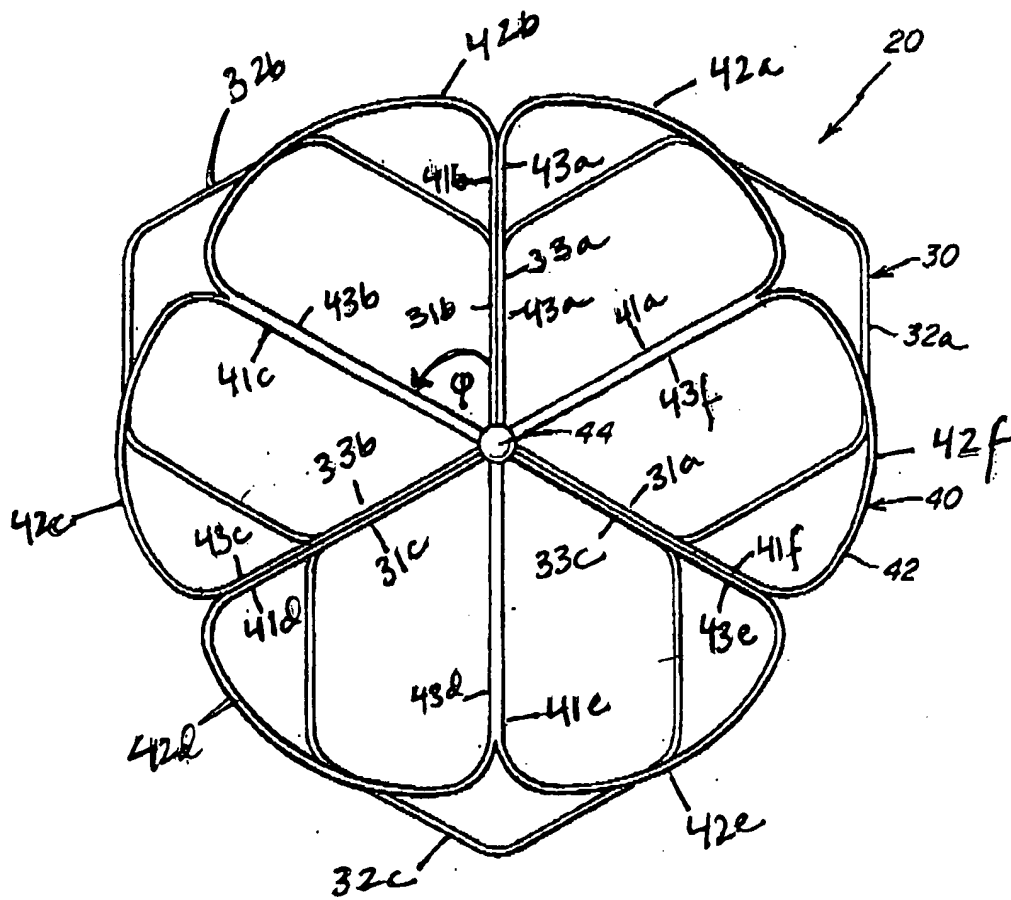


Fig. 5

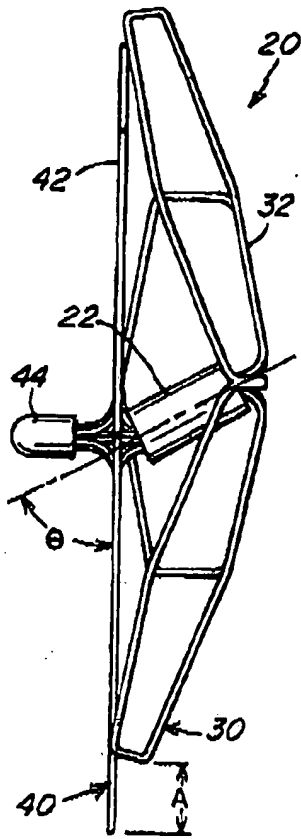


Fig. 6A

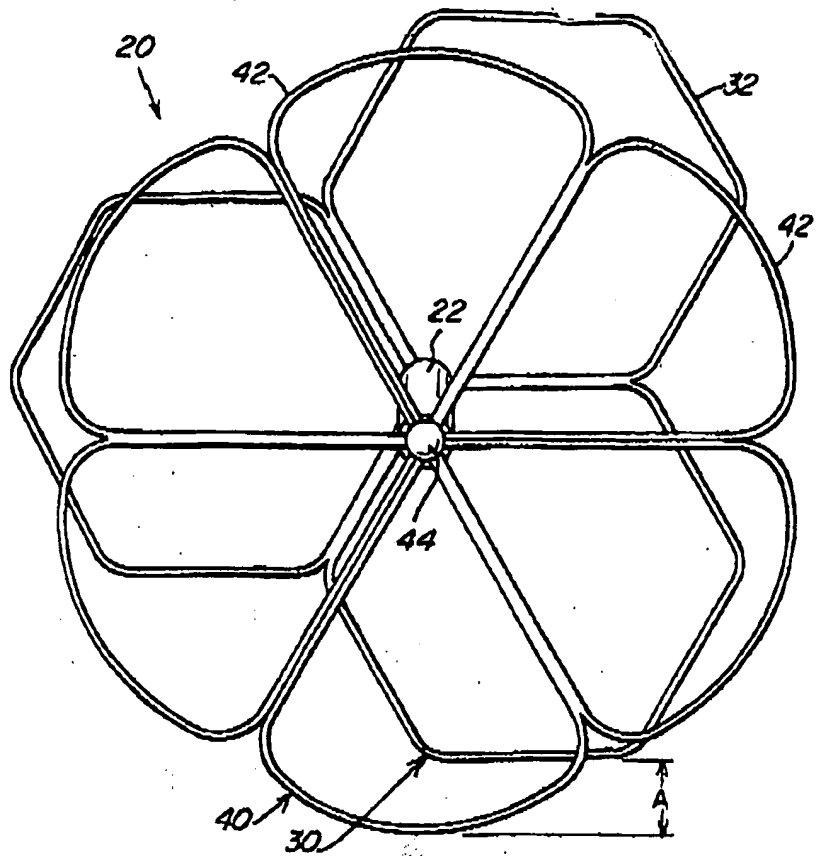


Fig. 6B

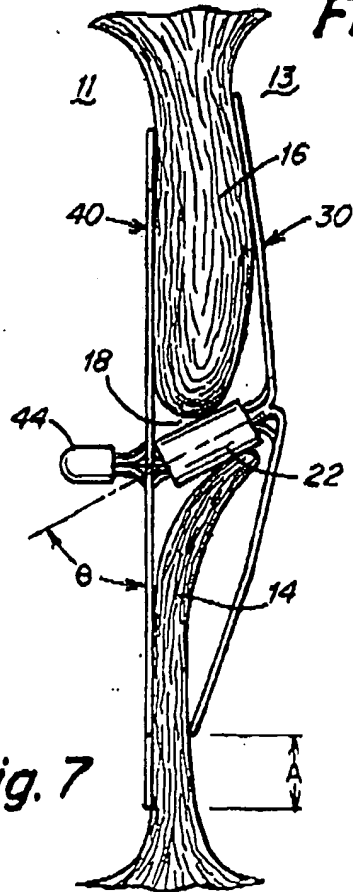


Fig. 7

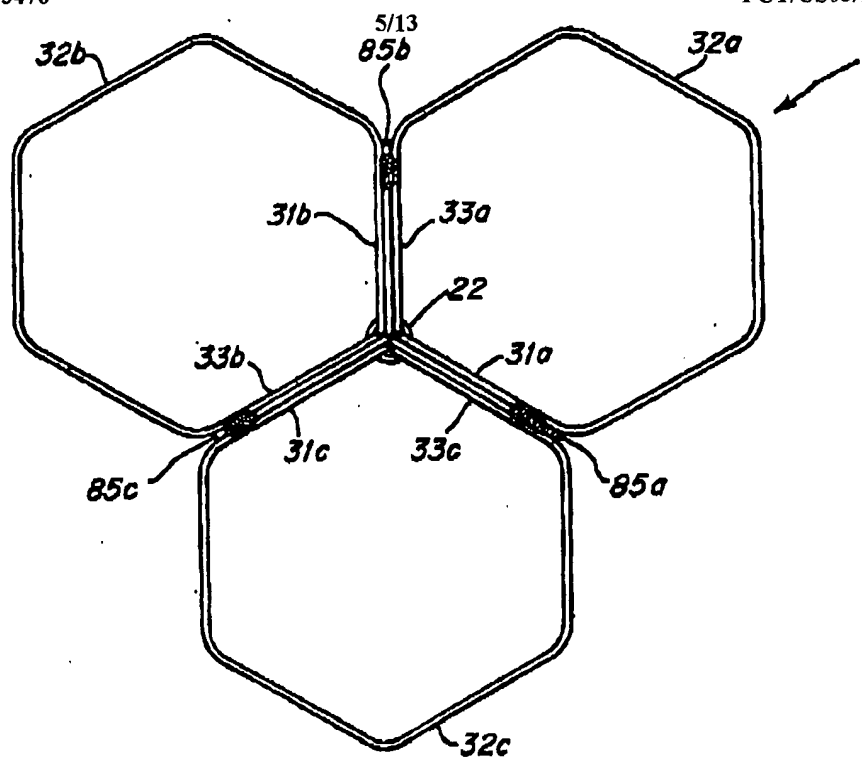


Fig. 8

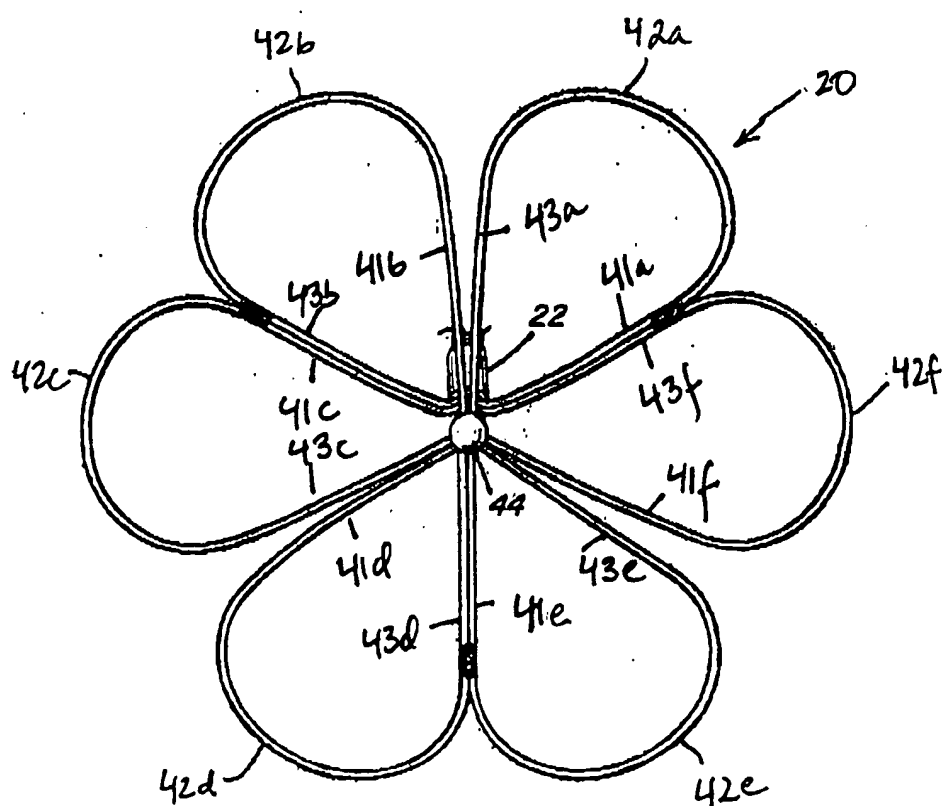
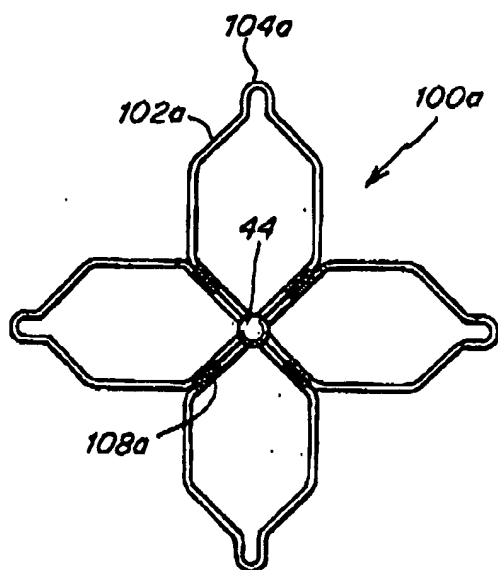
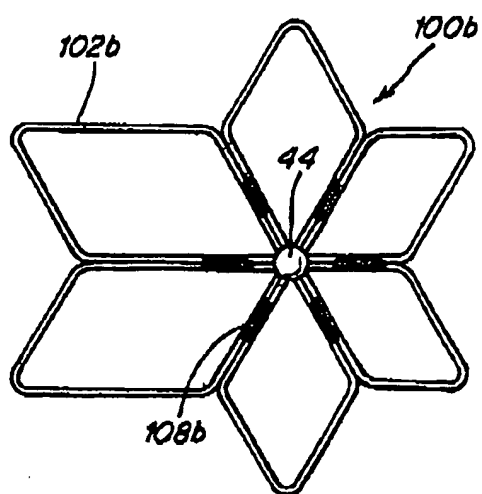
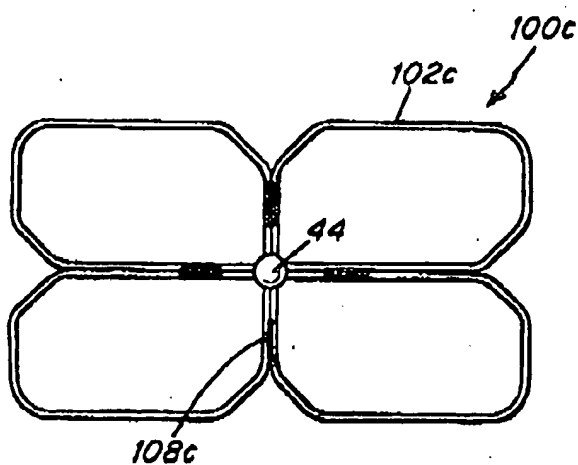
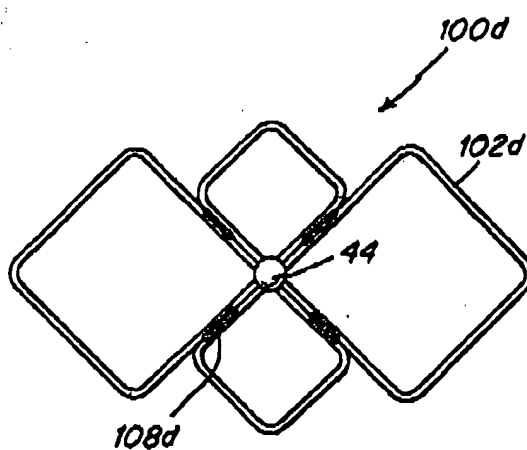


Fig. 9

*Fig. 10A**Fig. 10B**Fig. 10C**Fig. 10D*

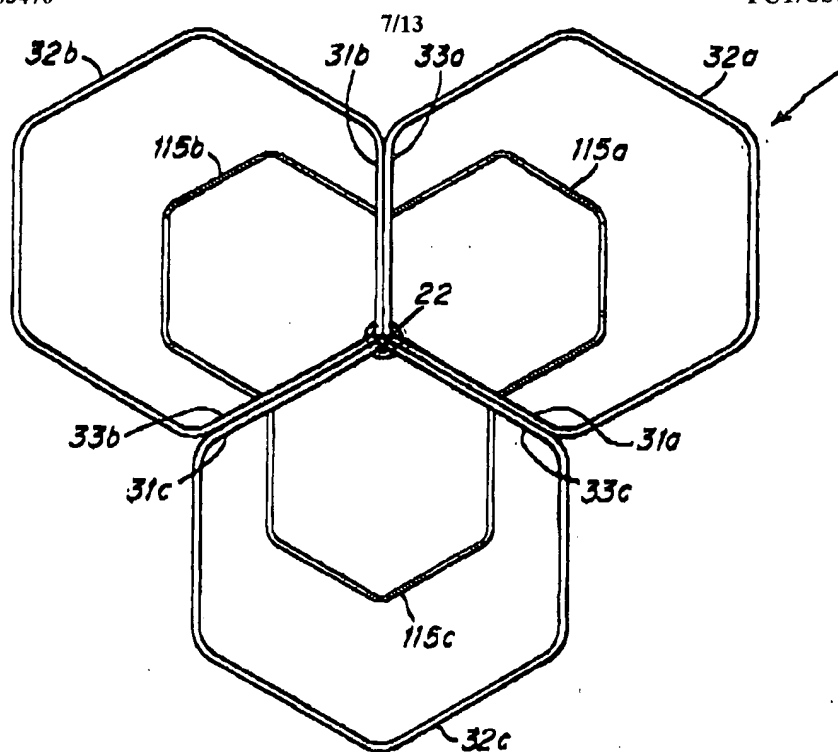


Fig. 11

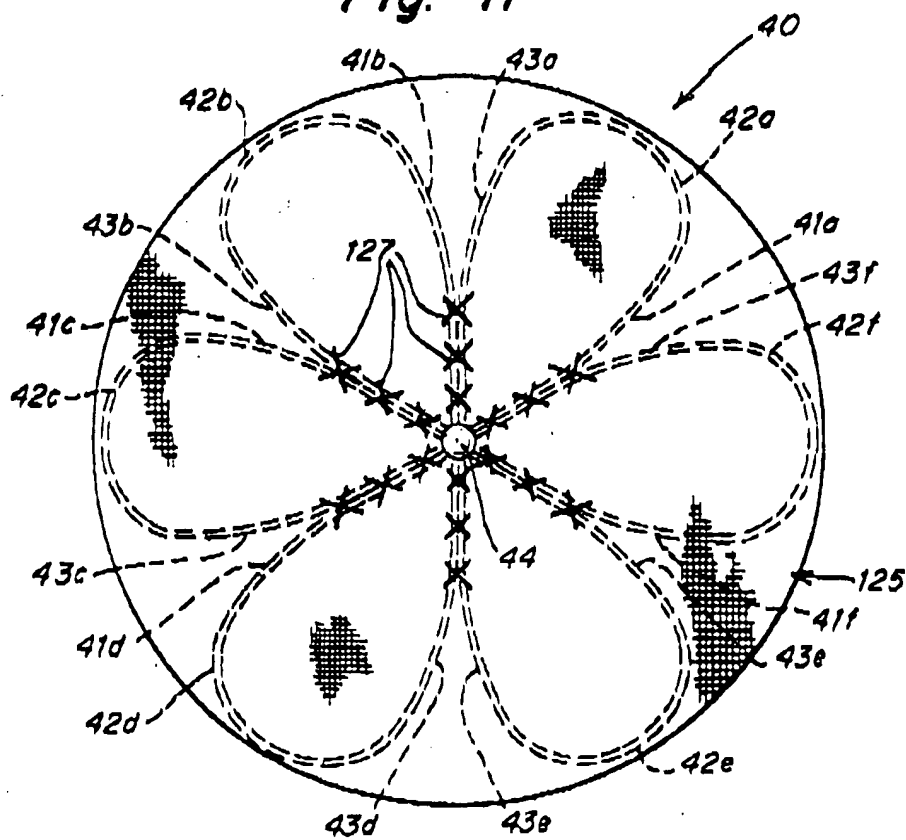


Fig. 12

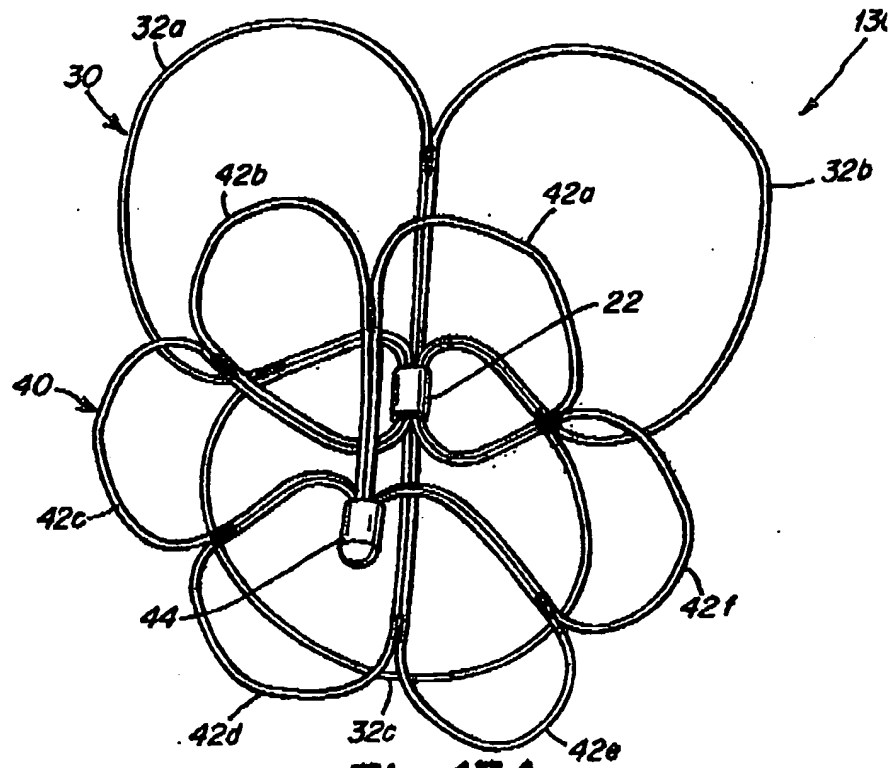


Fig. 13A

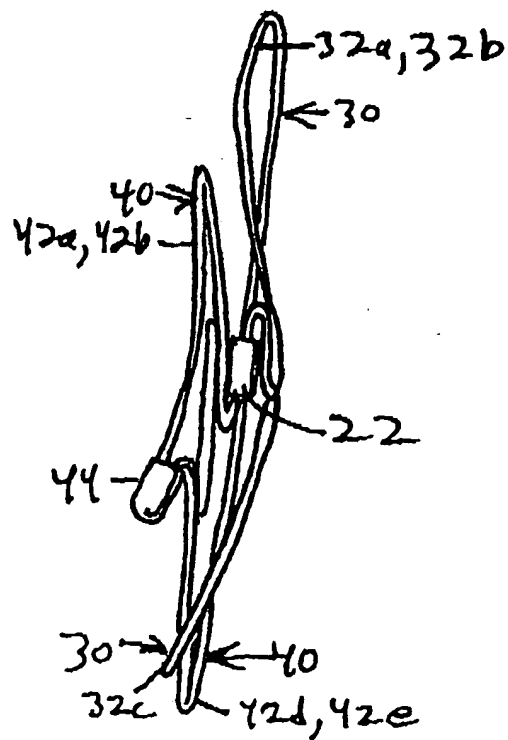


Fig. 13B

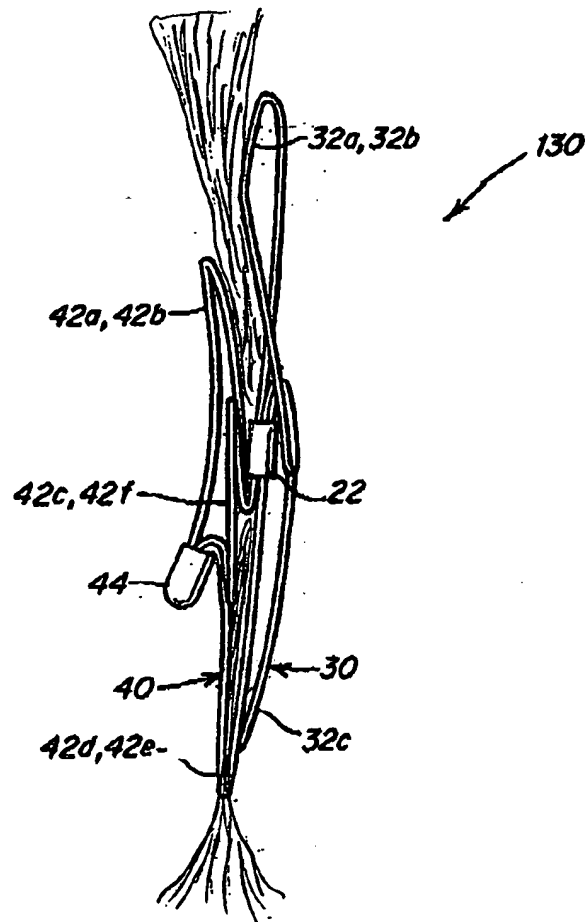


Fig. 13C

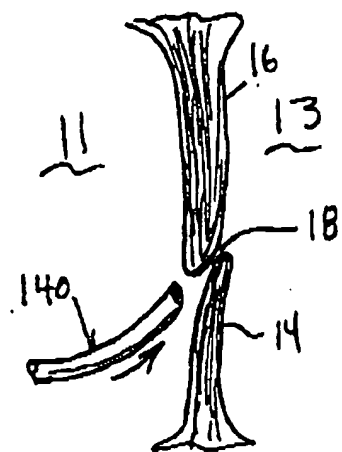


Fig. 14A

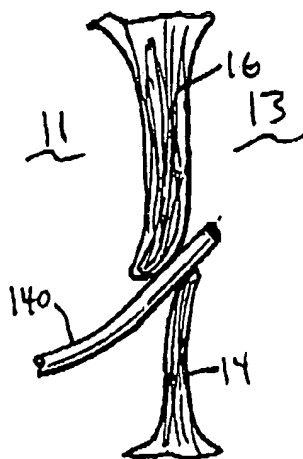


Fig. 14B

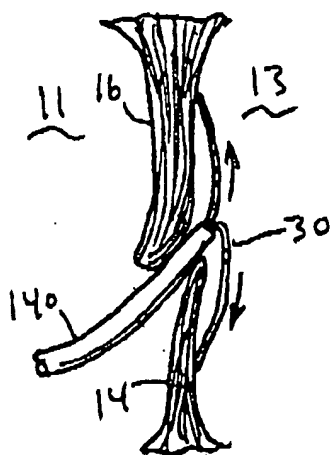


Fig. 14C

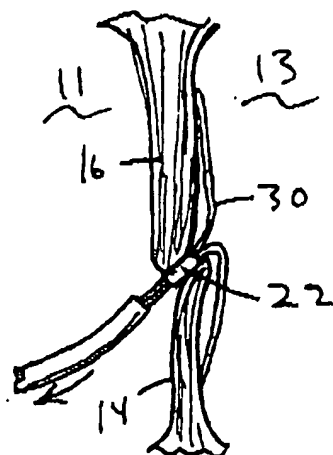


Fig. 14D

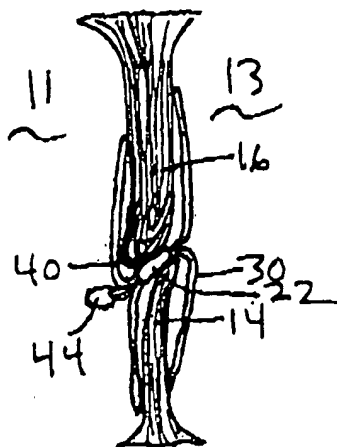
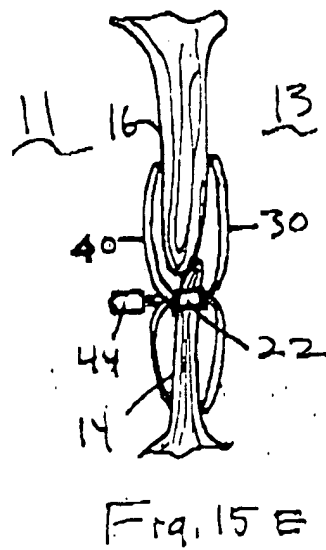
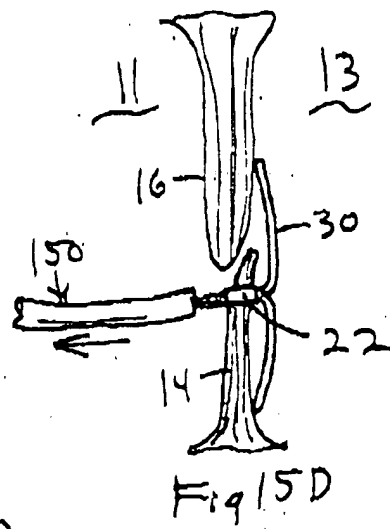
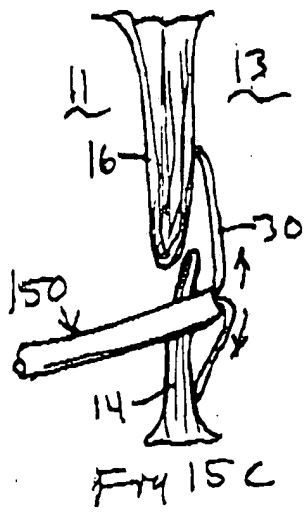
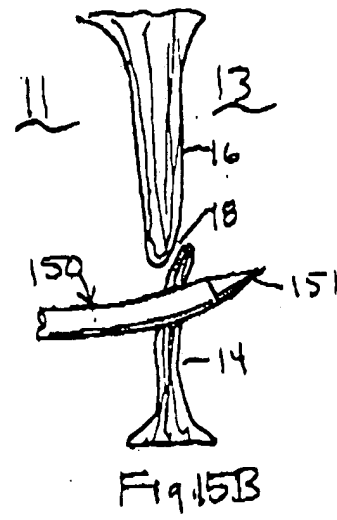
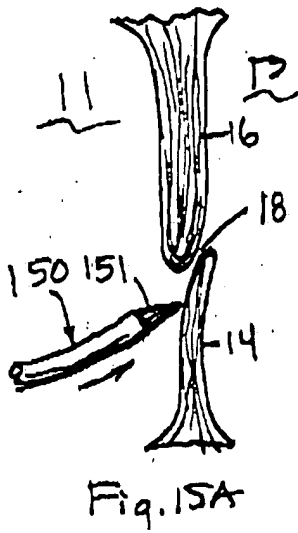


Fig. 14E



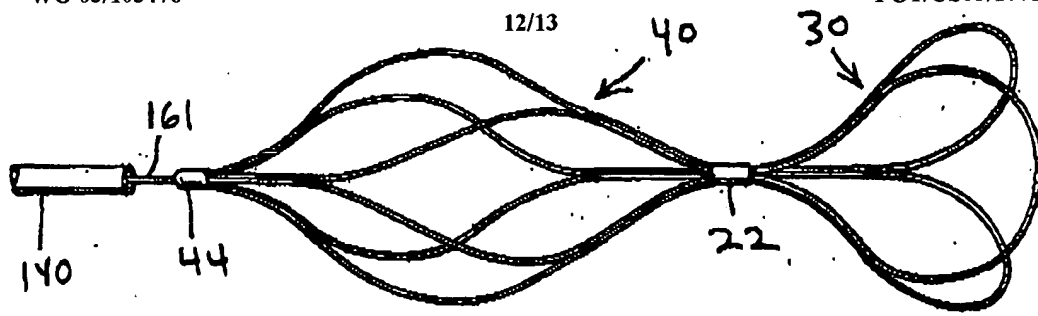


Fig. 16

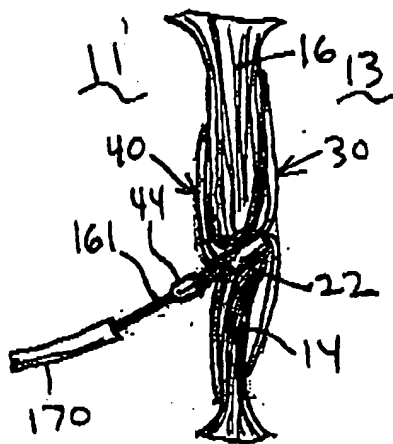


Fig. 17A

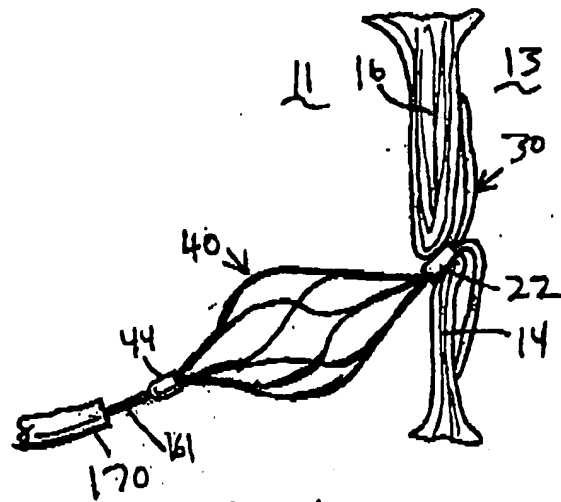


Fig. 17B

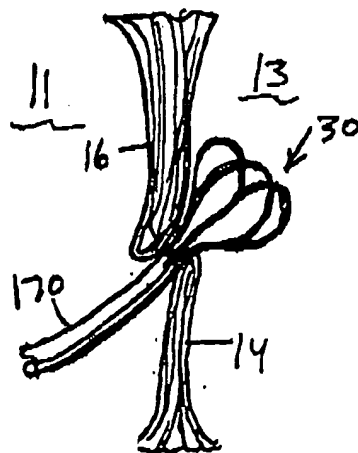


Fig. 17C

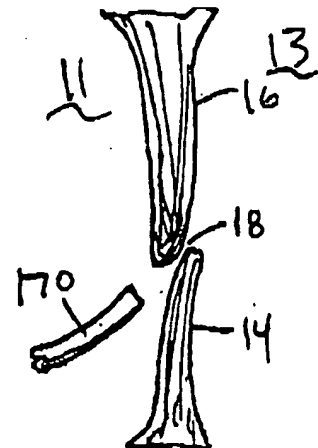


Fig. 17D

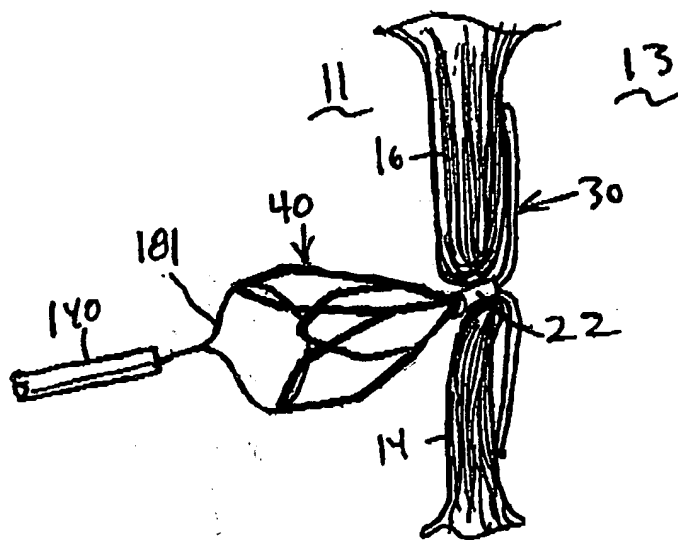


Fig. 18